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Recent Advances and Future Directions for Quality Engineering

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The origins of quality engineering are in manufacturing, where quality engineers apply basic statistical methodologies to improve the quality and productivity of products and processes. In the past decade, people have discovered that these methodologies are effective for improving almost any type of system or process, such as financial, health care, and supply chains.

This paper begins with a review of key advances and trends within quality engineering over the past decade. The second part uses the first part as a foundation to outline new application areas for the field. It also discusses how quality engineering needs to evolve in order to make significant contributions to these new areas. © 2015 The Authors *Quality and Reliability Engineering International* Published by John Wiley & Sons Ltd.

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1. Introduction

This paper is a reflection on the future of the field of quality engineering in light of its current state, which too often is solely associated with manufacturing. Frankly, our field faces a very bright future as we begin to break some of the shackles of our past. Historically, people view quality engineering as the set of theories, methods, and strategies for the improvement of quality, productivity, and reliability purely in manufacturing. We, in the field, contribute to this perception. For example, the American Society for Quality (ASQ) Quality Engineer certification and the current *ASQ Quality Engineer Handbook*[1] tend to emphasize mostly manufacturing examples of quality engineering. However, there are many complex, highly significant, and contemporary problems that require appropriate adaptations of many of the basic tools within quality engineering. The future of our field depends on how our classic quality engineering tools evolve to meet these new challenges.

For the last two decades, many industrialized countries have been experiencing tremendous amount of pressure in their economy to prevent manufacturing jobs to move to countries where the labor market is governed by less restrictive rules and abundance of supply. This concern was somewhat comforted by attempts to create more knowledge-based societies in industrialized nations and also with more emphasis on the service sector.

For the last decade, we have come to a stark realization that when the basic manufacturing flees, so do the knowledge and experience that accumulated over the years. As a result, competition grows ever fiercer, which has led to recent attempts in claiming back the manufacturing and retaining all that it brings in terms of labor, know-how, and competitive edge in the global market. Manufacturing in industrial countries has to, however, take a different shape to retain competitiveness as becoming more agile and flexible.

The future manufacturing environment, even for the simplest products, will be governed by robotics to improve the productivity. Ever cheaper and high-tech sensors for collecting massive amounts of data will extract valuable information for process and product improvement. This development will generate complex unit operations, each of which is being part of an even more complex process or series of processes. Therefore, any attempt to process and product improvement to increase productivity, reduce waste, and guarantee sustainability under the umbrella of quality engineering will have to take into account the complexity of the problem in this new data-rich environment. More methodology and application-oriented research will be urgently needed to keep up with the growing demand from industry.

People are also beginning to realize that the field of quality engineering has ample opportunities for application in many diverse areas beyond manufacturing such as the service industry, finance, health care, and supply chains. The key to these applications is that quality engineering improves processes as well as products. This new focus on improving processes in these new areas lies at the heart of the future of our field.

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The future of quality engineering, however, faces some serious challenges. A very real issue facing the profession is the growing divide between academic research and practitioner needs. Now, more than ever, practitioners need academia to focus on the real problems that practitioners face, especially as quality engineering evolves in order to meet the needs of the new application areas. One of the major purposes of this paper is to start building a bridge between the two communities.

The single most significant factor that drives the academia/practitioner divide is funding, which is a major driver of academic research, especially government funding sources. Too often, the people who control these funding sources are less interested in practitioner needs and more interested in 'new and exciting areas of statistics and industrial engineering'. Areas that even have the smell of being mature tend not to be well funded, while areas considered as 'sexy', at least for the moment, are well funded. Practitioner needs generally are not an important factor in these decisions, even when these needs provide new contexts that open the door to the next new and exciting area.

The next several years will see a plethora of articles in the industrial statistics/quality engineering journals on big data, computer experiments, new variations on optimal experimental design, and Bayesian methodologies. Some of these journal articles will have a major impact on practice. Regrettably, many will be purely of academic interest. Thus, a major objective of this paper is to start a conversation with that goal in mind of trying to identify problems of interest for both practitioners and academia. We hope that such a dialogue will lead to new methodological advances. Ideally, these new advances then lead to exciting new areas for scholarly inquiry.

This paper is a reflection of the current state and the future of quality engineering. Admittedly, our views are shaped by our academic and practical experience over the years, but some of important topics might have been overlooked. We further make no claim to provide a comprehensive review of the literature. As appropriate, this paper cites some of the current works in quality engineering. Generally, the papers that we cite are comprehensive reviews of their specific area within quality engineering/industrial statistics such as Woodall and Montgomery[2] for process monitoring and control. This paper reflects the spirit of much more work that has appeared in such traditional industrial statistics journals as *Quality Engineering*, the *Journal of Quality Technology*, *Technometrics*, and *Quality and Reliability Engineering International*. People interested in the future of quality engineering need to invest the time to keep current in our field through these journals. We encourage them to review the past several years of these journals for more insights.

2. Recent advances

2.1. *Extending standard methodologies to hard problems*

Industrial statistics, which forms the core of quality engineering, is a relatively mature field. Six Sigma programs continue to emphasize such basic tools as Shewhart control charts and factorial experimental designs, which have been in use for decades now. These basic tools are extremely valuable, but they are also relatively simple. The quality engineer often encounters real problems that require more sophistication. Many of the more sophisticated methods have been developed for design of experiments and process monitoring. Unfortunately, the development of the appropriate theory, methods, and tools for these real situations is a hard problem in and of itself and represents possible significant advances in our field.

2.2. *Experiments with hard-to-change and easy-to-change factors*

Experimental design and analysis are a fundamental tool in quality engineering. The historical industrial statistics approach to experimental design assumes that all of the factors are equally easy to change to their levels. This assumption is the foundation for all of the current Six Sigma training on the use of experimental design. Unfortunately, many real quality engineering problems involve some factors with levels that are much harder to change than for the other factors.

Many quality engineers/industrial statisticians learn about classical agricultural 'split-plot' experiments that also involve some factors that are harder to change than others. The analysis of these classical experiments is well understood and uses ordinary least squares to estimate the model. As a result, the analysis uses treatment means in a manner similar to completely randomized designs when all of the factors are equally easy to change. However, agricultural experiments are much larger than most industrial experiments and use more replication, which is the reason that people can construct split-plot experiments with analyses based on treatment means. Industrial experiments often have minimal or even no replication, which makes the analysis of a split-plot experiment much more complicated.

Jones and Nachtsheim[3] provide a nice review on the recent work on industrial split-plot experiments. We now understand quite well how to conduct two-level industrial experiments within a split-plot structure and how to analyze them. The most recent versions of such software as Minitab (Minitab Inc., State College, PA, USA), JMP (SAS Institute Inc. Cary, NC, USA), and Design Expert (Stat-Ease Inc., Minneapolis, MN, USA) can handle these types of experiments quite well.

Experiments designed to support a second-order model, often used in the later phases of response surface methodology (RSM), present special challenges. Jones and Nachtsheim[3] also summarize the recent work in this area as well, which focuses on two basic approaches. One uses optimal design strategy to develop the design, estimates the model using generalized least squares, and then uses restricted maximum likelihood or residual maximum likelihood as the basis for the analysis. The second approach builds experimental designs that allow the use of ordinary least squares to estimate the model. JMP can build and analyze optimal split-plot designs under its custom design feature. The most current versions of Minitab and Design Expert do not handle the second-order case.

The recent advances in handling hard-to-change and easy-to-change factors are quite significant. Quality practitioners now have the appropriate tools and methods to address these very common situations, at least for the cases where all the factors have only two levels. Clearly, we see these current advances continuing. In addition, two important emerging areas are optimization, especially for second-order split-plot response surface designs, and more complicated nesting structures.

Using experimental results to optimize processes and products is an integral feature of quality engineering. Split-plot experimental structures provide unique challenges. For completely randomized experiments, the set of tools provided under the RSM framework is well established and in use with great success. However, the literature is rather sparse on optimization when there are restrictions on randomization on an RSM study, especially for multiple responses, which often are of interest. We expect in the near future a flurry of research activities in this area.

Daniel[4] points out, 'Nested designs (some factors held constant, others varied within each "nest") are common in industrial research. The *larger the system* under study, the more likely it is that such plans will prove *the more convenient* or *even the only possible* ones' (p. 275). Unfortunately, a lack of proper techniques in designing and analyzing these experiments appears to have stunted the development of this area. Clearly, we expect more work with complicated nested structures to follow the recent advances in split-plot industrial experimentation.

The recent work on split-plot industrial experimentation highlights some of the academia/practitioner divide. There seems to be a tendency in academia to focus on ever more complicated methodologies with a growing dismissive stance towards 'trivial' problems as they do usually not result in any scientific publication. From a practitioner's perspective, there is nothing trivial about any situation that requires a split-plot design. Clearly, academia should focus on pushing the frontiers in developing new techniques to handle more specific situations; however, we cannot afford to ignore difficulties that restrictions on randomization found in the split-plot structure create for practitioners, especially novice experimenters. Therefore, there remains tremendous room in rendering the already existing techniques for split-plot experiments more accessible and easily interpretable to most practitioners. In an applied field such as quality engineering, research and academia should always keep one eye on the practicability and dissemination of the methodologies that are being developed.

2.3. *Profile monitoring*

Traditionally, standard control charts monitor a process based on a single characteristic of interest or a set of characteristics of interest. For example, a writing instrument company routinely takes samples (based on rational subgrouping) hourly from an injection molding process that produces pen barrels. The operator measures the critical outside diameter in order to guarantee the fit of the cap and the barrel.

The quality characteristics of some processes, however, are much more complicated. Figure 1 plots the dose–response curves for a specific pharmaceutical. The entire curve or profile represents the quality characteristic, not a single number or some small set of numbers. An important recent advance in statistical process control is the development of sound procedures to monitor such profiles over time.

Monitoring profiles raises interesting challenges. What do we mean by an in-control process? How do we measure the difference between an observed profile and those in in-control state? What are the statistical properties of such measures? These are nontrivial questions; however, they go to the heart for developing an appropriate monitoring procedure.

Woodall *et al.*[5] gives a nice overview of this area as it was beginning to develop. The book by Noorossana *et al.*[6] summarizes much of the work during the 2000s. The general line of research either uses different models for capturing the profile or tries to handle correlation structures. While there is some work carried out on Phase I data, many applications in this area primarily concentrate on Phase II applications that assume that the appropriate control chart parameters are known.

Clearly, there is much more work that needs to be carried out in this area. The field needs more research on Phase I studies to answer properly the question of 'how does an in-control process look if the characteristics of interest are profiles?' How can we estimate what constitutes an in-control process during a Phase I study when the process in all likelihood is not in-control? Such questions are fundamental for practitioners as they attempt the full implementation of profile monitoring.

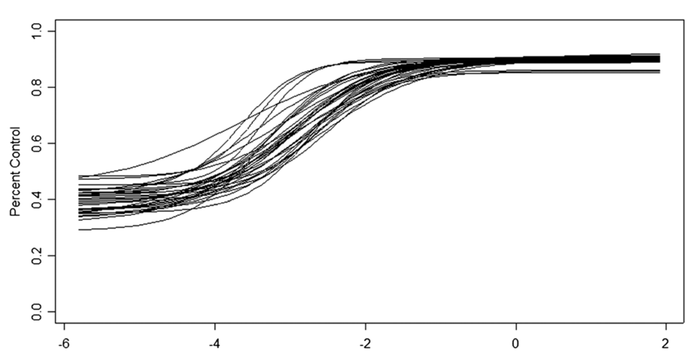

Figure 1. A dose–response curve for a pharmaceutical (Williams *et al.* [7])

Another future direction considers alternative ways to perform dimension reduction on the profiles. An interesting approach uses feature extraction methods from chemometrics such as principal component analysis for unsupervised learning and partial least squares for supervised learning. We believe that we have to revisit and expand on the works of John MacGregor and his collaborators when it comes to bringing chemometrics methods into our field particularly in profile monitoring.[8–11]

The importance of bio-based manufacturing as in the production of biopharmaceuticals, biofuels, and food ingredients in industrial countries makes this research particularly crucial in the near future as these are mostly batch processes yielding profiles of various process variables during production. Monitoring these variables is essential in ensuring the quality of the final product. Through the available analytical tools such as near infrared and Raman spectroscopy, the full-scale exploitation of the chemometrics methods is still needed in bio-based production. Also, in many cases, the practitioner must take the batch-to-batch variability into account when defining the in-control state. A serious question then is how to define the batch-to-batch effect on the basic profiles.

2.4. Computer experiments

Many modern products and processes are sufficiently complex and expensive that physical experimentation is too costly and/or too time-consuming endeavor. As a result, an increasing number of engineers and scientists use complex computer models based on first principles as a surrogate for physical experimentation. The resulting experiment manipulates via some protocol the inputs to the computer code.

The results from the computer code are deterministic, which raises serious statistical issues. Running the same values for a set of inputs produces exactly the same answer. As a result, there is no true statistical error. Therefore, basic principles such as randomization, replication, and blocking relevant in physical experiments are not a concern in deterministic computer experiments. The common methods used in the analysis of the data collected from these experiments reflect this different reality. Ultimately, these analytic methods are interpolation methods ensuring that the prediction at experimental points actually matches the data.[12] Gaussian stochastic processes (GaSP) and kriging are the most popular analytical approaches. Typically, the GaSP approach uses some form of a Bayesian argument for the interpretation of the results. In practical terms, however, the Bayesian analysis provides a justification for the tuning parameters in the interpolation scheme.

The standard computer experiment text is Santner, Williams, and Notz.[13] Interestingly, the primary focus of this text is on analysis. This text concentrates on using GaSP as a basis to predict the behavior of the response where there are no data. Kennedy and O'Hagan[14] is the seminal paper for the Bayesian approaches to GaSP. A nice recent review paper is Zhang and Notz.[15]

Critical design issues do abound. For most computer experiments, the entire experimental space is of interest; thus, the true response surface often displays nonlinearity. Consequently, many analysts prefer space-filling designs as opposed to factorial designs commonly used in physical experiments. Especially popular are such approaches as uniform and Latin hypercube designs, because of their appealing projective properties.[16–20] Of course, one of the major concerns when it comes to space-filling designs is the curse of dimensionality: It becomes increasingly more difficult to properly 'fill the space' as the dimensions of the space become larger, that is, more factors to study.

The curse of dimensionality is a major obstacle to overcome, especially when running time is a concern, for example, in computational fluid dynamics. Each experiment in these cases often takes hours, if not days or even longer, to complete. Therefore, the aim usually shifts to finding surrogate models to replace computationally expensive runs. These surrogates are called meta-models or 'model of the model'.[21–25]

It should be noted that meta-models are approximations of the approximations (computer model) of the true underlying phenomenon. In that sense, proper 'spot checks' for verification and validation purposes at both stages (at the computer model and even the real system if possible) need to be performed. We have not seen a detailed study that includes cost concerns in detail about this particular issue. Such a study will certainly be extremely useful for practitioners in providing some guidelines in validating the meta-models properly. We refer the reader to scientific journals in various engineering fields where examples of meta-models abound this could provide insight into the objectives with such models, thus helping in shaping appropriate problems.

The solution to the validation of the meta-models often involves experimentation at different fidelities. That is, an initial set of experiments is run in a coarse grid from which areas of interest in the experimental region are expected to be identified, and a new set of experiments will be run at a finer grid to conduct a more elaborate analysis. While there has been much interest in this area particularly in computational fluid dynamics applications,[26–31] we expect to see more research and application work in multifidelity computer experimentation and in multiscale modeling in the near future.

In some cases, people use the computer code to do simulation experiments. In these cases, the practitioner generates a small random error on at least some of the inputs. The computer code propagates these small input errors to produce some variability in the response. The literature, however, mostly focuses on the deterministic case. Often, but not always, simulation experiments are similar enough to physical experiments that classical experimental approaches work well. This insight opens up new possibilities of applications of experimentation in service sectors such as finance and health care where traditional physical experimentation is often infeasible because of complexity of the system and/or safety issues. Running experiments, for example, on discrete event simulators of such systems can provide valuable information on the bottlenecks in the system, improve service quality, and even generate opportunities for making these systems robust to uncontrollable factors, for example, to ensure smooth functioning of an emergency room irrespective of the fluctuations in the patient arrival rate.[32]

More research and applications are certainly needed in this area in order to take full advantage of the strengths of both simulation modeling and experimental design. A major obstacle is that many practitioners do not grasp the tools for the design and analysis of simulation and computer experiments. There is a strong need for making available tools more accessible to the practitioners,

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particularly in the choice of experimental design, the number of experimental runs, sequential experimentation methods, and interpretation of the analysis results. Both academia and practitioners need to appreciate what the modeling entails, what the goals of the modeling are, and how this will influence the proposed design.

Categorical factors provide another challenging task in computer experiments. Such factors are of great concern particularly in the GaSP analysis, which inherently assumes that the correlation functions essential for the interpolation are quantitative factors.[33–35] We believe that more academic and applied work can be expected to be published in this area particularly when it comes to optimization applications using simulation experiments.

2.5. Statistical thinking

Statistical thinking is not a new concept. Britz *et al.*[36] do an excellent job of introducing the concept of statistical thinking. Their definition of statistical thinking includes three fundamental principles:

1. All work is a series of interconnected processes.
2. All processes vary.
3. Understanding variation and reducing variation are keys to success.

The key to this definition is that statisticians are the experts in dealing with variability. Statisticians know how to identify sources of the variability in data, to quantify the amount of variability, and to make intelligent decisions in the face of variability.

The statistical thinking movement makes the point that often the biggest contribution that quality practitioners can make is to have senior managers to understand variation and its sources. Roger Hoerl and Ron Snee are two of the leading advocates for statistical thinking. Hoerl and Snee[37] is a wonderful text that goes into the philosophy and application of statistical thinking for improving business performance. Hoerl and Snee[38] is a thought-provoking article. Hoerl and Snee consistently point out that the future of our profession depends upon the value that we add to our organizations. Statistical thinking and its application go to the heart of our value proposition.

Historically, data analysis has been a critical aspect in the jobs of industrial statisticians and quality engineers. Unfortunately, data analysis is not the future of quality engineering, at least not in North America. It is too easy to ship data analysis offshore to subcontractors with cheaper labor costs, as many organizations already have performed, especially in manufacturing. Saving money and being efficient with time are no-brainers for companies. Quality professionals must recognize that they have huge opportunities to provide value to their organizations in a world where someone else does data analysis. What is the effect on our jobs in this new world? What would be the new role of the quality engineer if she no longer has to analyze data? We believe this is the most crucial issue when it comes to 'statistical thinking'.

Statistical thinking is about expecting and accepting the stochastic nature of our processes. It understands that there can be a signal hidden in this noisy environment and that extracting this signal can help us to unlock the mysteries plaguing our processes. Statistical thinking and statistical analysis, properly carried out, support the scientific method, especially as an iterative learning process for solving problems. In that regard, we should welcome this new environment with open arms as it will free us from the labor intensive tasks and allow us to contribute better to the understanding of the world around us.

Many Six Sigma implementations illustrate how industrial statisticians/quality engineers can evolve from basic data analysts to important change agents by teaching managers, especially, the importance of statistical thinking. Often the biggest value that a statistician can provide is the insight that all work occurs in processes, that each stage of the process provides sources of variation, and that the key to improving quality, productivity, and reliability is to understand these sources of variation. The combination of process thinking with a proper understanding of variation makes industrial statisticians/quality engineers extremely valuable, far more valuable than simple data analysts.

2.6. Applications in areas other than manufacturing

In the 2000s, more and more people began to realize that we can use the basic principles of quality engineering to improve processes and systems in general. Suddenly, quality engineering no longer was restricted to the manufacturing sphere. Six Sigma and Lean were a big reason for this evolution as companies began to realize the potential benefits of applying these tools to such areas as service functions, risk management, security, and health care. Companies found major rewards by applying basic quality engineering concepts to accounts payable, product delivery, and customer relations.

Quality Engineering has published several articles that detail how practitioners can expand the horizons of quality engineering beyond manufacturing. Bisgaard,[39] which is his 2005 Youden Address from the Fall Technical Conference, is a classic article. In addition, Ronald Does' Quality Quandaries column has been another rich source, especially with regard to health care.[40–46]

The food industry is another area with potentially quite challenging application possibilities. While proper experimentation techniques are well recognized at the product development level and date back to some of the earliest cases of experimental design applications, we find the more modern approaches in process improvement to be more scarcely applied within this industry or that the methods are failing to meet the challenges that current food producers face.

2.7. Advances in software

Current software can do much more sophisticated statistical analyses to support quality engineering. Some of the new capabilities include the following:

- hard-to-change versus easy-to-change factors;
- integrated variance optimal designs;
- space-filling designs (computer experiments); and
- GaSP (computer experiment modeling).

Each new release brings new and welcomed features.

Nonetheless, there still are many other features that practitioners require. One of the most urgently needed features involves methods to analyze large data sets, which slowly are becoming the norm rather than the exception in many applications. For example, methods based on latent structures in statistical process control applications are still nonexistent in many statistical software packages. The practitioners who would like to use these techniques often have to resort to obtaining the latent structures and using them in statistical process control applications in two separate steps. Moreover in many cases, statistical process control software options lack the online monitoring components. As a result, the practitioners lack the ability to interactively record data and check the state of the process in many cases without the use of specifically written macros. The more prevailing appearance of the latent structures-based methods seems to be limited to specialized chemometrics software such as Umetrics (MKS Instruments, Andover, MA) and Unscrambler (CAMO, Oslo, Norway). The quality engineer working in the new data-rich environments can simply not afford to work with generic statistics software lacking the capability of efficiently applying chemometrics and data-mining techniques to process improvement studies.

Most commercial statistical software companies have found themselves in a predicament of competing with R, which is free software for statistical analysis that has the support of an ever-growing and dedicated user community. In the past, the main disadvantage of using R for the novice practitioner was the lack of pull-down menus and relative difficulty in coding the user specified functions. In recent years, however, there have been several attempts to make R more accessible to users from various backgrounds and interests, with contributions to the graphical user interface starting to resemble commercial options as in the case of R studio. For example, it is now possible to access R from Excel, which is very commonly used in business and finance applications. The attempts to make R more user friendly will only be amplified in the near future allowing for any quality engineer to have very cost-effective access to an extremely powerful statistical analysis toolbox.

As the software becomes more sophisticated, practitioners must exercise extreme caution with software 'claims'. In the current design of experiments applications, for example, some software vendors essentially say, 'We understand the proper experimental protocol; so, you do not need to worry about it. Give us the experimental factors, the levels, and the experimental constraints. We will give you the optimal design for your needs. Even better, when you have your data, we can do all the analysis for you. You do not need to think or worry about it!' A consequence of these claims is the extreme potential for major disasters.

Software is an extremely important tool; however, it requires intelligent use. Just like any other tool, one must know and appreciate its use. No matter how good the software is, we must realize that 'Sir Ronald Fisher in a box'/'George Box in a box' does not exist. Data collection requires intelligent collaboration among the statistical analyst and the subject matter experts. Someone must ask the right questions. Everyone must think carefully about the underlying science/engineering/subject matter, which then must be translated into the proper experimental protocol and the analysis. Software is an essential tool, but it is only a tool!

We regretfully admit that blind faith in the software packages is often a direct result of poor understanding of the underlying principles. This faith in turn tends to eliminate critical thinking that one should exercise early and often in statistical analysis. Statistics, by its very nature, speak to both our mind and our imagination. It is our admittedly biased view that this very fact makes it extremely exciting. Any attempt that may put shackles to either of these faculties when doing the statistical analysis should be received with extreme caution.

2.8. Global reach

The foundations of quality engineering were developed in North America and Japan. North America provided the statistical theory and methods applied to manufacturing. Japan brought forward foundational ideas for quality management, the 'soft tools', and emphasis on teamwork. The quality gurus were people like Shewhart, Deming, Box, Taguchi, and Ishikawa.

Today, quality engineering is truly a global phenomenon. A major driver is the movement of manufacturing away from North America to China, India, the 'Asian tigers' such as Korea, Singapore, and Malaysia, Mexico, and Brazil. The founding of the European Network for Business and Industrial in 2001 marked recognition in Europe for the need of quality engineering. People now understand that the quality engineering body of knowledge knows no borders.

The current thought leaders in industrial statistics/quality engineering come from across the globe now. Authors from Hong Kong, Singapore, Korea, and Europe produce contributions that rival and often exceed the contributions from North America and Japan. Currently, China is investing heavily into its universities to advance quality engineering in order to support the country's manufacturing juggernauts. Engineers in India are beginning to make great strides implementing good quality engineering practices.

Our body of knowledge is truly global in scope, in its generation, and in its dissemination. Editorial review boards of the major industrial statistics/quality engineering journals are truly global, as are the authors who publish in them. A recent editor of *Technometrics* is from Israel. The next editor of the *Journal of Quality Technology* is from Hong Kong, and the next editor of *Quality Engineering* is from Turkey. We now see a true proliferation of outstanding quality engineering conferences across the globe. Of special note is the Stu Hunter Research Conference, which is an invitation that only conference designed to bring together the thought leaders in industrial statistics/quality engineering. The first three conferences (2013, 2014, and 2015) emphasized North American and European researchers. Frankly, a major reason for the creation of the Stu Hunter Research Conference is the quality and the success of the annual European Network for Business and Industrial conference, where the top researchers and practitioners in Europe come together. The Stu Hunter Research Conference plans to include more researchers from Asia and other continents as well in future years.

Even ASQ has started ASQ Global with a stated desire to become Global ASQ. A truly Global ASQ is one that knows no boundaries and whose leadership at all levels reflects true global diversity. The society is making progress in this journey although it will take several years for most people to see the evolution.

3. Future directions

The recent trends that we have highlighted will continue to have traction over the short-term horizon. However, we see other areas emerging that will become increasingly important as researchers develop techniques and methodologies of value to practitioners.

3.1. Integrating quality engineering concepts across complex processes/systems

The quality profession's drive to provide organizational value often leads to problems involving very complex processes/systems. Solutions to these problems require a toolset and a mindset far beyond Lean–Six Sigma. Lean–Six Sigma often is extremely useful for tackling important subproblems. However, Lean–Six Sigma alone cannot provide successful resolution to these kinds of problems. Complex processes/systems often generate very large amounts of data from very different sources. Just the exercise of bringing together all of the relevant data alone is often a daunting task.

A good example of a very complex process is the developmental and operational testing of weapon systems. These projects are multiyear (in some cases, approaching 20 years!), have multiple stages, and involve different (and sometimes conflicting) objectives at each stage, and the parties involved often have competing interests. Too often, there are active disincentives for the sharing of data and for full collaboration/cooperation.

Complex manufacturing/business processes commonly have multiple stages, multiple locations (generally global), and multiple organizations (perhaps within the same company). These problems require true statistical thinking, especially with regard to how systems operate. Properly understanding the steps in the process is essential to success. Often, the first step is simply flowcharting the process at several levels, from a 50,000-ft perspective to a 10,000-ft perspective.

Once people understand the stages in their process, they may achieve reasonable success using statistical thinking to guide the application of the basic quality engineering tools. In many cases, organizations are not using the appropriate tools to address the basic problems within each stage of the process; thus, applying the proper tools leads to major successes. The traditional quality engineering tools can work well within well-defined process stages.

Increasingly, practitioners find that the standard quality engineering toolbox is not rich enough. As a result, we need to develop new methodologies specifically to cross the stages in these complex systems. Fertile areas for academic research include the proper design of quality management systems for complex processes, formal and informal Bayesian methods for combining disparate information, and belief networks.

These complex processes often involve highly elaborate projects with large amounts of data. As quality engineers and applied statisticians, we may like to think that this is the point that we step into the picture and improve the process. But the challenge certainly goes beyond the issues related to data analysis.

Good solutions to problems involving complex processes require interdisciplinary teams that function smoothly for the entire project. As a result, some of the lessons learned from Lean–Six Sigma apply to complex processes as well. The team needs a strong facilitator as it routinely addresses such questions as which quality characteristics to consider and how to quantify them and properly measure them. Good organizational psychology skills are essential to deal with such issues as establishing the role of each member of the team, developing action plans for short and long terms, and identifying bottlenecks that would hold the progress of the entire project hostage.

Project management skills also are vital. Consider, for example, that you are operating a shipyard and received an order for a large container vessel. Where do we start? How do we put the myriad of components together so that we can deliver the vessel in a timely manner while ensuring the high quality standards that our shipyard is known for? We now venture into new waters beyond our comfortable data analysis realm and into the territory of project management. Softer tools such as simple flowcharting (milestone), checklists, and Gantt charts become quite essential.

Project management is a well-established research field in its own right, but it would indeed be great to see in our journals more applied and academic work on the interaction between our field and project management with particular emphasis on case studies. We believe that our practitioners will greatly benefit from learning methodologies that will enable them to see the 'bigger picture' in complex projects on which they work.

3.2. Massive data sets

Issues with 'massive' data are not new. The definition of 'massive' changes depending on technology, but the basic question remains the same. One of the authors recalls working with ALCOA in the mid-1990s. ALCOA had a large amount of process data on its rolling process. Management's attitude was, 'Why do we need to plan experiments? We have all the data already. Just use it'. From management's perspective, these data represent the entire population of interest. As a result, they must contain all the answers to the organization's questions. The analysts simply need to 'mine' the data.

People ask similar questions today. We hear a great deal about data mining and machine learning. We now have virtually the entire population of data for some processes. The issues are how to distill the information to address important questions of interest. The problem often is that the data available cannot answer the questions of interest.

Vining[47] outlines the problems of retrospective studies (historical data), which are the basis for the overwhelming majority of massive data sets. Issues that he raises are the following:

- Historical data usually are those relatively easy to collect on an ongoing basis and not necessarily the data necessary to address the specific questions of interest.
- Many historical data sets include information that was important for solving a problem long ago, and people no longer know why those data were collected.
- Organizations typically run their processes within reasonably strict policies that minimize the data from drifting outside the 'normal' ranges. These protocols prevent the analysts from seeing potential interesting phenomena.
- Massive data sets generally suffer from severe problems with missing data.
- These data sets often have serious data quality issues due to recording errors or transcription errors.
- When interesting phenomena do occur in the data set, they occurred so long ago that no one can establish why these data were interesting.
- Most engineering and scientific massive data sets suffer from extreme oversampling.
- Typically, analysts are looking for a needle in a haystack with most massive data sets.

Massive data sets have tremendous issues related to data management: collecting the raw data from several disparate sources, transferring the data from one medium to another, cleaning the data, preparing the data for analysis, and of course maintaining the security of massive data. Most organizations discover sooner or later that mining massive data sets can cost significantly more in terms of actual information gained per person hour of analysis than a well-planned experiment.

Inherent to all historical/observational data is the ever-elusive difference between correlation and causality. It is extremely difficult to use observational data to make meaningful causal claims. The historical reason for the observations gathered is often based on past and solved problems and thus not tailored for unforeseen issues. Massive data sets exacerbate this problem by focusing on very simple correlations, often only pairwise, because of computing constraints imposed by the size of the data set. As a result, the correlations used in the analysis of massive data sets do not necessarily answer the research question in hand. It is insightful to recall that Sir Ronald Fisher developed factorial experimental designs and analyses as an alternative to analyzing purely observational data. Good experimental protocols followed by appropriate analyses do provide a meaningful basis for causal claims. Even more important, such an approach requires far fewer data and, thus, expense. In some cases, analysts can extract very efficient pseudo-factorial experiments within massive data sets that yield extremely interesting results.

In today's world, we have massive data warehouses, some on planetary scale. The demands to develop techniques to analyze such data are immense. Frequently, people fail to consider whether the data are information rich or information poor. Information-poor data sets essentially involve looking for a very few, very small needles in a massive haystack. Such data sets often suffer from significant oversampling and tight process protocols. As a result, the most informative data points typically are the outliers, because they provide meaningful information, if for no other reason, because they are different. Information-poor data warehouses have little likelihood of any success to address meaningful questions of interest. On the other hand, information-rich data sets have many large needles in much less hay. As a result, massive, information-rich data warehouses are extremely interesting, challenging, and important. A very important research question is how to distinguish information-rich data sets from information poor.

Standard statistical approaches are not valid and not informative for massive data warehouses, even when the data are information rich. Too often, subject matter experts consider statisticians as serious impediments with their insistence on controlling Type 1 error and on trying to do traditional statistical inference. As a result, the leaders in analyzing these massive datasets are subject matter experts, led by scientists, engineers, and computer scientists. However, these people fundamentally do not understand that for massive datasets, the most interesting phenomena often are the outliers. An important statistical issue then is being able to define what constitutes an outlier.

Ultimately, we believe that it is best to view any analytical technique for massive data sets within the context of exploratory data analysis. Exploratory data analysis looks at observational data to develop interesting follow-up questions. This approach entails an understanding that using observational data in such a preliminary way requires a strategy for identifying and dealing with outliers. Typically, analysts then follow up using robust estimation techniques that mitigate the impact of these outliers. It is at this point that we suggest analysts looking at massive data sets to change the algorithm. Rather than mitigating the impact of the outliers, the analyst should create pseudo-experiments based on the outliers that then become the basis for identifying interesting follow-up questions. In this way, we can consider more fully the reasons for doing the analysis, what questions we need to address, and how to create an appropriate analysis that facilitates our decision-making process. Often, this approach should lead to focused, formal experimentation.

Generally, it is a challenge to explain to the management what kind of information can and cannot be extracted from massive data. Management believes that the massive data set, because of its size, must contain all the answers to its questions. Very rarely does management understand the fundamental issues with unplanned observational studies. It is our concern that the analysis of massive data is vulnerable to misuse that result in improper conclusions with respect to cause and effect, which can be drawn far too easily. As a community, we need to address this issue in greater detail and warn our practitioners about making tangential or even outright wrong conclusions based on the analysis of massive data. The problem touches on the same issues as with complex systems and, thus, also the need for cross-disciplinary collaborations and research.

3.3. Image data

Image data are becoming more and more prevalent and important to decision making, especially in health care. Kafadar[48] provides the introduction to a special issue of the *Annals of Applied Statistics* devoted to imaging in neuroscience. It is becoming clear that the basic analysis of image data is becoming 'mature', which can be seen with the development of R solutions for the field. Currently, people use these data primarily in an inspection mode. Mature techniques do not currently exist to transform the use of image data into process monitoring outside of the pass/reject scope of control.[49]

Formal statistical approaches for analyzing image data often use likelihood ratio as an important part. The cumulative sum control (CUSUM) chart is simply a clever use of the likelihood ratio statistic. As people develop likelihood approaches for analyzing image data, they should be able to adapt these likelihood methods to create CUSUM-like statistical process control techniques to accommodate image data.

Applications of image data in quality engineering have so far mostly focused on quality inspection. For even fast throughputs, we can use image analysis to evaluate the objective state of each product and ensure that 'bad' products never reach the customer. This is particularly relevant for food and pharmaceutical industries, as customer safety is often the number one concern. One of the authors is quite familiar with a state of the art facility in Peru for inspecting fruit immediately prior to packaging. It is amazing to see the equipment at work, making decisions using image data.

In many cases, the new imaging systems will provide an opportunity to do 100% inspection. Using every item produced by a process then poses new challenges for process monitoring. It is one thing to separate good product from bad. However, it is another to take advantage of the information provided by such an inspection process. Ignoring this information flies in the face of efforts of almost hundred years in quality engineering initiated and established by giants like Shewhart, Deming, Juran, and Box. The information provided by these inspection processes provides an opportunity to improve the quality of our processes and products. In many cases, we can build new processes that greatly reduce, and in many cases eliminate, inspection in the first place; hence, the need is to develop statistical monitoring techniques for these data. In that regard, we need to revisit some of our tools based on sampling strategies and adapt them to this new world of census data. Also, new statistical monitoring methodologies for image data are a logical next step for statistical monitoring of profile data. We expect a great deal of exciting work in the very near future.

3.4. Experiments involving functional data (profiles)

Textbook experimentation primarily focuses on the analysis a single response of interest, especially in terms of optimization. There is much work on optimizing a set of responses; however, the approaches always map the set of responses to a single number as in the case of a desirability index. Box[50] notes that not all responses are suitably described by a single digit, a scalar depicting the result after an intervention. There are many situations where the real question of interest centers on how a function (a surface, a profile, or an image) changes over time and/or space given specific experimental conditions. The experimental purpose is not to optimize; rather, it is to characterize the surface's behavior. An example helps to illustrate this point.

Storm *et al*.[51] discuss an application involving the US Air Force's Aerial Refueling Airplane Simulator Qualification flight test protocol. There were several responses, and each of which was a time series. In this paper, the authors discretized the series to nine-time slices. The main objective of the experiment was to understand how the response surface for each response changed over time. One goal was to be able to create an animation of the surface over time based on the predicted model. Figure 2 as follows, which is Figure 6 from this paper, illustrates the basic concept.

There are many applications areas that ripe for these kinds of experiments, ranging from the chemical process industry to food technology/engineering to pharmaceuticals to the machining of parts. This research area parallels in many ways statistical process monitoring of profiles. As a result, we expect to see a great deal of activity in this area over the next several years.

One particularly interesting area of research is when both the factors and the responses follow time series. In which case, the factor levels are not constant; rather, they exhibit patterns in magnitude during experimentation. Such input factors are common, especially in the process industries, where factors seldom remain constant as a result of random process disturbances or changes due to

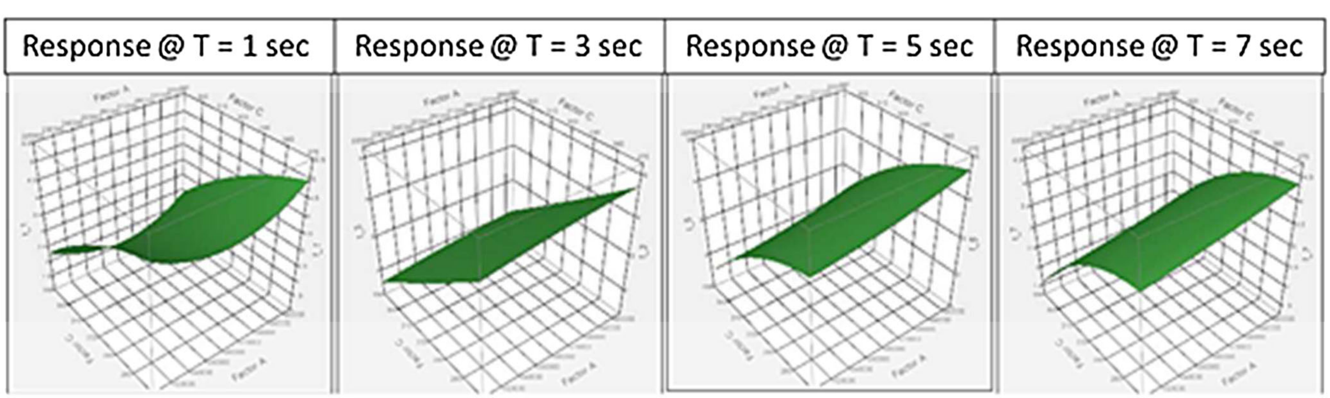

Figure 2. Response surface from different time slices. Source: Storm, Hill, and Pignatiello [51]

unforeseen control actions. As a result, it often is best to view such factors as time series. In these cases, designing the experiments and properly analyzing them cannot be accomplished with the existing methods.

3.5. Greater emphasis on reliability

An interesting definition of reliability is quality over time. Customers today are beginning to demand highly reliable products and processes. In this climate, people expect products and processes to perform with high quality over the entire expected lifetime of the product/process.

The standard textbooks for the statistical analysis of reliability data are Meeker and Escobar,[52] Lawless,[53] and Nelson.[54] These texts focus primarily upon model estimation and inference in the presence of censoring for highly skewed distributions. They do discuss regression models for reliability data and accelerated life testing. However, the focus of accelerated life testing in these texts is on obtaining data more quickly in order to estimate life times at use conditions. The typical approach for planning accelerated life tests assumes a completely randomized design.

Simple accelerated life tests are not sufficient to create products and processes to the reliability standards that customers are beginning to demand. There is a strong need for better experimental designs and analyses for reliability data that allow practitioners to identify the factors that produce the desired levels of reliability. Freeman and Vining[55,56] and Kensler *et al*.[57,58] discuss approaches for reliability experiments for censored Weibull data that take the experimental protocol into account. The expressed intent of these papers is to glean substantive information about which experimental factors influence the product/process reliability with an eye for improvement.

In addition, there is a strong need to develop process control techniques for reliability data to ensure that the product/process maintains the expected reliability standard. Steiner and MacKay[59] propose five Shewhart approaches to detect shifts in the process mean for censored reliability data. Zhang and Chen[60] develop an exponentially weighted moving average approach for such data. Dickinson *et al*.[61] propose a CUSUM approach and provide a detailed comparison of the various approaches.

There is much more work to be carried out in this area; however, we must recognize the very real challenges inherent to developing new methodologies. Historically, experimental design and analysis as well as statistical process control assume that the data follow roughly a normal distribution and that there is no censoring of the data. Censoring occurs when the experimenter stops a life test before failure. Almost all reliability data involve highly skewed censored data. Traditional experimental design and statistical process control researchers must learn a new context for their research. This new context is quite different and highly nuanced with respect to the typical normal theory methods.

3.6. Innovation

Not long ago, simply building better quality was significant innovation. Now, most people view high quality as an expectation. The new issue is how to delight customers through improved current products and through completely new products that customers never imagined. Box and Woodall[62] give a nice overview of this area, particularly for quality practitioners.

An important issue is how quality engineering can facilitate innovation. Quality engineering clearly has an important role for incremental innovation. Traditional design and analysis of experiments have a large role here. Creating products that consumers never imagined is much harder. Actually, the soft tools in quality engineering, such as brainstorming, have strong potential.

Thomke[63] makes a strong case for the use of good experimentation to advance innovation. He especially urges managers to pursue sequential experimentation, one of the historic areas of quality engineering. One of the problems with our field is that we fail to recognize the new emerging areas and how we, as a profession, can make a significant impact. Iterative learning through experimentation is one of our strengths. However, even now, many of us fail to see how we can apply this to facilitate the innovation process within our organizations to create exceptional organizational value. Thomke and Mazi[64] is a very interesting piece on how business should pursue experimentation in the pursuit of innovation.

The January 2012 issue of *Quality Engineering* has a strong innovation focus. Of particular note is Bisgaard,[39] which won the ASQ Brumbaugh Award for that year. These papers exhort quality professionals to remarket our skills and wisdom in order to facilitate innovation within our organizations. In addition, Peter Merrill writes a regular column in *Quality Progress* that explains very well the role of innovation in our current economic environment.

3.7. Proper training of practitioners

Six Sigma brought quality engineering into the hands of subject matter experts, which on the whole, was a good thing. However, too many Six Sigma Black Belts after being certified felt that they knew all that there was to know about the standard quality engineering tools, especially experimental design and statistical process control. But as can be seen in the work performed on follow-up questions and interviews with industry, there still seems to be a steep learning curve when applying these tools.[65,66]

It is crucial to realize that the typical Six Sigma Black Belt training barely scratches the surface of the quality engineering field. These people get about 4 weeks of training in 3 months. The basic problem is that they often do not know when to call an expert to help with the planning or the analysis. Failure to call in an expert can lead to disasters!

Recent software developments exacerbate the problem. Software does not know when the user is misapplying statistical techniques. As software tries to automate more of the planning of the data collection and the follow-up analysis, more of these problems will occur.

There is a strong need for organizations to ensure that there is appropriate follow-up training with emphasis on 'when to call an expert'. Master Black Belts need to take the lead with this effort. Unfortunately, too often the Master Black Belts themselves do not have sufficient statistical background, which is OK only so long as they know when to call the expert. Appropriate experts can be graduate educated statisticians within the companies or qualified external consultants. The point simply is that organizations need to be aware of the critical role that these experts play in the success of quality/productivity/reliability improvement programs.

3.8. Statistical engineering

Hoerl and Snee[38] propose a new discipline called 'statistical engineering' that deals with how best to use known statistical principles and tools to solve high-impact problems for the benefit of humanity. Statistical engineering involves the tactical integration of statistical thinking with the application of statistical tools and methods at the operational level. It drives best practice for the application of statistical methods based on solid understanding of statistical thinking principles. Proper applications of statistical engineering typically involve the appropriate selection and use of multiple statistical tools integrated into a comprehensive approach to solving problems.

Much of the focus of statistical engineering is on large unstructured complex problems. The problems where quality engineers/industrial statisticians have the greatest opportunity to make significant impact are not simple textbook analyses. It seems that the quality engineering field has evolved to a point where the further development of theory needs fresh insight from practical applications. As has been in the general evolution of many sciences, statistics may have reached a point where an engineering subfield is viable or even necessary.

We must develop a mindset that brings order out of chaos. As a result, the key to statistical engineering is a fundamental understanding of the scientific method and how strategically to deploy it to solve these large unstructured complex problems. The first step of the scientific method is to clearly define the real problem. The next step is to identify the root causes. Typically, discovery of the root causes requires keen insight based on what George Box described as an inductive–deductive process. This discovery process almost always requires data, which then means that proper data collection is also fundamental to statistical engineering. Once we have the data, we must perform appropriate analysis and interpret the results with full understanding on the constraints and their impact on the proper interpretation of the results. The basic tools of quality engineering are essential to the theory of statistical engineering.

The April 2012 issue of *Quality Engineering* is devoted to statistical engineering. We strongly encourage people to read these articles and to see the potential contained in this vision of statistical engineering. As practitioners, we must appreciate how statistical engineering should guide our evolution in the new environment, especially with regard to large, unstructured, and complex problems.

4. Summary

Today, quality engineering/industrial statistics stands at a crossroads. Frankly, the field must evolve in order to survive. However, experts in the field as well as practitioners need only to look back at the fundamentals of our field to see an extremely productive path forward. There are many rich opportunities for people in our field to make significant contributions. The moment has come where we need to expand the reaches of our field to new areas, where better quality, productivity, and reliability are just as important as they still are and have been in manufacturing.

Industrial statisticians/quality engineers combine a solid appreciation of process thinking with a fundamental understanding of variability and its causes. This combination is extremely powerful as society deals with increasingly complex problems that require the tools of quality engineering. Quality engineering experts and practitioners simply must seize the opportunity and adapt accordingly.

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